MAR 2 9 2012

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: **K110737**

1. Submitter's Identification:

BIONIME CORPORRATION
NO 694, RENHUA ROAD, DALI DIST., TAICHUNG CITY, TAIWAN 412
Contact Person: Mr. Roy Huang
Phone Number: 886-4-24951268
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Date Summary Prepared: March 26, 2011

2. Name of the Device: Rightest Blood Glucose Monitoring System GM700

3. Common or Usual Name: Glucose test system

Device Product Code	Device Class	Panel/ Regulation number
NBW; System, Test, Blood Glucose, Over-the-Counter	Class II	Clinical Chemistry 21 CFR 862.1345
LFR; Glucose Dehydrogenase, Glucose	Class II	Clinical Chemistry 21 CFR 862.1345
JJX; single(specified) analyte controls (assayed and unassayed)	Class I	Clinical Chemistry 21 CFR 862.1660

4. Device Description:

Our Rightest Blood Glucose Monitoring System GM700 consists of the following devices: Rightest Blood Glucose Meter GM700, Rightest Blood Glucose Test Strip GS700, Rightest Control Solution GC700, lancing device and sterile lancets. The Rightest Blood Glucose Meter GM700, Rightest Blood Glucose Test Strips GS700, and Lancing Device are manufactured by BIONIME Corporation. The Rightest Blood Glucose Meter GM700, when used with the Rightest Blood Glucose Test Strips GS700, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM700 is verified by the Rightest Control Solution GC700.

A Rightest Blood Glucose Monitoring System GM700 kit box may contain different bundled items.

5. Intended Use:

The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertips, palm and forearm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM700 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strip GS700 is for use with the Rightest Blood Glucose meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The Rightest Control Solution GC700 is for use with the Rightest Blood Glucose meter GM700 and Rightest Blood Glucose Test Strip GS700 to check that the meters and test strip are working together properly and that the test is performing correctly.

6. Predicate Device Information:

The Rightest Blood Glucose Monitoring System Model GM700 is substantially equivalent to the brand of Rightest Blood Glucose Monitoring System noted below.

Name:	Rightest Blood Glucose Monitoring System Model GM550
Device Company:	Bionime Corporation
510(K) Number:	K092052.

7. Comparison to Predicate Devices:

Specification Comparison

Similarities		
Item	Rightest BGMS GM700 (New Device)	Rightest BGMS GM550 (Predicate Device k092052)
Minimum Sample Volume	1.0 microliter	
Test Time	5 seconds	

Measuring Range	20-600 mg/dL
Operating Relative Humidity	10 ~ 90%
Battery Life	About 1000 tests
Monitor	LCD display
Meter Storage Conditions	-10 ~ 60℃ (14 ~140 ℉)
Test Strip Storage Conditions	4 ~ 30℃ (39 ~86 ℉), < 90% relative humidity
The unit of measurement data	Fix on mg/dL
Sample	Capillary whole blood

Specification Comparison

Differences		
Item	Rightest BGMS GM700 (New Device)	Rightest BGMS GM550 (Predicate Device k092052)
Interference	Uric acid ≧ 10 mg/dL Xylose ≧ 10 mg/dL	Uric acid ≧ 10 mg/dL
Memory Capacity	1000 blood glucose test results with date and time	500 blood glucose test results with date and time
Power Supply	One CR2032 battery	Two CR2032 batteries
Power Saving	Press the main button for 3 seconds.	Press the main button for 4 seconds.
Meter Dimension	99 mm × 46 mm × 17.5 mm	90.6 mm × 46 mm × 16.5 mm
Meter Weight	57.0 ± 5 g with battery	53.0 ± 5 g with batteries
Coding	Smart autocoding	Auto coding
Hematocrit Range	30-55%	30 - 60%
LCD display area	52.6 mm × 32 mm	47 mm × 33.5 mm
Strip Reagent	1.FAD-glucose Dehydrogenase (FAD-GDH) 9.0% 2.Potassium ferricyanide 53.7% 3.Non-reactive ingredients 37.3%	1.Glucose Oxidase (GOD) 14.8% 2.Potassium ferricyanide 39.5% 3.Non-reactive ingredients 45.7%
Measurement Technology	Dehydrogenase Electrochemical Sensor	Oxidase Electrochemical Sensor
Operating Temperature Range	6 ~ 44℃ (43 ~111 ℉)	10 ~ 40℃ (50 ~104 ℉)
Back Light	No	yes

Control solution	L1, L2, L3, L4, L5	Normal and high level

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the Rightest Blood Glucose Monitoring System GM700. The evaluation included precision, linearity, interference and hematocrit.

9. Discussion of Clinical Tests Performed:

System Accuracy Study:

The accuracy study of the Rightest Blood Glucose Monitoring System GM700 was performed by comparing whole blood (plasma equivalent) glucose values on the Rightest meter with plasma glucose values on a lab instrument.
A total of 109 patients were participated. The study result demonstrates that the accuracy of Rightest Blood Glucose Monitoring System GM700 met the acceptance criteria.

User Performance Study:

A User performance study was performed to demonstrate that lay consumers could obtain accurate results using the subject device. The study was performed using capillary whole blood from fingertip, palm and forearm sample sites. The study result shows substantial equivalence to Rightest Blood Glucose Monitoring System GM700 used in finger, palm and forearm position.

10. Conclusions:

Results of performance evaluation of the Rightest Blood Glucose Monitoring System GM700 demonstrate that the devise is substantial equivalence to the predicate device, Rightest Blood Glucose Monitoring System Model GM550.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bionime Corporation
c/o MDI Consultant, Inc
c/o Jigar Shah
55 Northern Blvd, Suite 200
Great Neck, New York 11021

MAR 2 9 2012

Re: k110737
Trade Name: Rightest Blood Glucose Monitoring System GM700
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, JJX, LFR
Dated: March 26, 2012
Received: March 27, 2012

Dear Jigar Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110737

Device Name: **Rightest Blood Glucose Monitoring System GM700**

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ____X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K110737